

REMARKS

Claims 1-10 are pending. Claims 2-4 and 8-10 are withdrawn from consideration as being drawn to a nonelected invention. Claims 1 and 5-7 were examined. Claims 1 and 5-7 were variously provisionally rejected under the doctrine of obviousness-type double patenting. Claims 1 and 5-7 were variously rejected under 35 U.S.C. § 102(e).

By this amendment, claims 1 and 7 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification including, for example, at page 38, lines 12-14.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Restriction Requirement

The Examiner has deemed the restriction requirement proper and final for this application. In doing so, the Examiner has rejected the genus-species relationship of the independent and dependent claims in favor of a combination-subcombination relationship.

When asserting that the specific sequences set forth in claims 2-4 and 8-10 are not generically set forth in claims 1 and 7, respectively, the Examiner states that “[c]learly these are different and specific nucleic acid sequences which would not anticipate nor make obvious one another as ISS sequences.” Office Action, page 3. However, in the §102(e) rejection, the Examiner asserts that the cited references teach “specific sequences which anticipate a sequence comprising 5’-C, G, pyr, pyr, C, G-3’ (see example SEQ ID NO: 13 and 14).” Office Action, page 7. Asserting that the sequences of SEQ ID NO: 13 and 14, for example, anticipate the sequence of claims 1 and 7 appears contrary to the statement cited above in which the Examiner found that different and specific nucleic acid sequences “would not anticipate nor make obvious one another as ISS sequences.”

Although the restriction determination is deemed final, Applicants respectfully maintain that the ISS sequences in the withdrawn claims are species of the ISS sequences in the independent claims and, thus, respectfully continue to traverse the restriction requirement.

Provisional Rejections under the Doctrine of Obviousness-type Double Patenting

Claims 1 and 5-7 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 6, 7 and 11 of U.S. Pat. Application No. 09/802,686 (Pub No. US 2001/0046967) and over claims 1, 5, 6 and 17 of U.S. Pat. Application No. 09/802,445 (Pub No. US 2002/0107212 A1). Applicants respectfully traverse these provisional rejections.

Applicants thank the Examiner for bringing these applications to attention. Applicants respectfully point out that the instant application and the two cited applications are commonly

owned, were all filed on the same day, March 9, 2001, and all claim priority to the same date, March 10, 2000. Thus, Applicants request withdrawal of these provisional rejections.

Rejections under 35 U.S.C. § 102(e)

Claims 1 and 5-7 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Krieg *et al.* (U.S. Pat. No. 6,218,371 B1, herein “the ‘371 patent”). Claims 1 and 5-7 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Krieg *et al.* (U.S. Pat. Application Pub. No. US 2003/0050263 A1, herein “the ‘263 application”). Applicants respectfully traverse these rejections.

As an initial matter, Applicants note that the Examiner’s position in maintaining the restriction requirement appears to be in conflict with the position taken for the §102(e) rejection, as discussed above. Given that Applicants maintain the position that the ISS sequences in the independent and dependent claims of the invention have a genus-species relationship, the following is based on the other reasons why the cited references do not anticipate the claimed invention.

The claimed invention is directed to a method of reducing severity of a symptom of virus infection in an individual infected with a virus through administration of a composition comprising an ISS-containing polynucleotide to the individual in an amount sufficient to reduce severity of a symptom of virus infection. The claimed ISS comprises the sequence 5’-C, G, pyrimidine, pyrimidine, C, G-3’. As amended herein, in the claimed method, neither an antigen of the virus nor an immunostimulatory cytokine is administered in conjunction with administration of the composition.

On the contrary, the ‘371 patent “relates to synergistic combinations of immunostimulatory CpG oligonucleotides and immunopotentiating cytokines.” ‘371 patent, column

1, lines 12-14. Throughout the disclosure, the '371 patent describes "methods and products for inducing a synergistic immune response using a combination of a CpG oligonucleotide and a cytokine." '371 patent, column 3, lines 6-8.

For a claim to be anticipated by a reference, the reference must teach each and every element of the claim. As noted above, the claimed invention excludes administration of an immunostimulating cytokine in conjunction with the ISS-containing polynucleotide. The '371 patent does not teach the claimed invention.

With regard to the '263 application, the Examiner cites paragraphs 14-20 as teaching "that the ISS sequences can be used to treat viral infections." Office Action, page 8. Applicants respectfully submit that paragraph 14 of the '263 application does not describe the use of ISS sequences for treating viral infections. With regard to paragraphs 15-20 of the '263 application, Applicants respectfully point out that the '263 application is a continuation-in-part application filed on August 16, 2001, more than one year after the priority date of the instant application. Accordingly, since those paragraphs do not appear in the priority document for the '263 application, they are not citable as art under 35 U.S.C. § 102(e).

Thus, Applicants respectfully submit that neither the '371 patent nor the '263 application anticipates the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(e).

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001600. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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